

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., )  
FOREST LABORATORIES HOLDINGS, LTD., )  
MERZ PHARMA GMBH & CO. KGAA, and )  
MERZ PHARMACEUTICALS GMBH, )

Plaintiffs,

v.

COBALT LABORATORIES INC., LUPIN )  
PHARMACEUTICALS, INC., LUPIN LTD., )  
ORCHID PHARMACEUTICALS INC., ORCHID )  
CHEMICALS & PHARMACEUTICALS LTD. )  
(d/b/a ORCHID HEALTHCARE), TEVA )  
PHARMACEUTICALS USA, INC., UPSHER- )  
SMITH LABORATORIES, INC., WOCKHARDT )  
USA INC., and WOCKHARDT LIMITED, )

Defendants.

C.A. No. 08-21-GMS

**DEFENDANT ORCHID CHEMICALS AND PHARMACEUTICALS, LTD.'S  
OPENING BRIEF IN SUPPORT OF ITS RULE 12(B)(2) MOTION TO  
DISMISS FOR LACK OF PERSONAL JURISDICTION**

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Dated: March 3, 2008  
852227 / 32657

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## I. NATURE AND STAGE OF PROCEEDINGS

This is an action for patent infringement brought pursuant to the Hatch-Waxman Act, 21 U.S.C. § 255(j). Plaintiffs Forest Laboratories, Inc. (“Forest Labs”), Forest Laboratories Holdings, Ltd. (referred to herein, together with Forest Laboratories, Inc., as “Forest”), Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as “Merz”) (collectively, “Plaintiffs”), claim that they own all substantive rights in U.S. Patent No. 5,061,703 (“the ‘703 patent”), which allegedly covers the drug identified as “Namenda<sup>®</sup> brand” memantine hydrochloride tablets. *Complaint* at ¶¶ 27, 28. The Merz entities are German corporations that allegedly are the sole assignees of the ‘703 patent. *Complaint* at ¶¶ 3, 4, 27. The Forest entities assert that they are the exclusive U.S. licensees of the ‘703 patent, and hold New Drug Application (“NDA”) No. 21-487 for Namenda<sup>®</sup> brand memantine hydrochloride tablets. *Complaint* at ¶¶ 1, 2, 28. Forest Labs is a Delaware corporation having a principal place of business in New York City, and Forest Laboratories Holdings, Ltd. is an Irish corporation. *Complaint* at ¶¶ 1, 2. The ‘703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for Namenda<sup>®</sup>. *Complaint* at ¶ 28.

Defendant Orchid Chemicals & Pharmaceuticals Ltd. (“Orchid India”) is an Indian corporation having a principal place of business in Chennai, India. Defendant Orchid Pharmaceuticals, Inc. (“Orchid Delaware”) is a Delaware holding corporation, and is a wholly-owned subsidiary of Orchid India.

Plaintiffs’ Complaint alleges, pursuant to 35 U.S.C. § 271(e)(2)(A), that Orchid India and Orchid Delaware (collectively, “Defendants”) have infringed the ‘703 patent by submitting an Abbreviated New Drug Application (“ANDA”) for memantine hydrochloride tablets. *Complaint* at ¶¶ 45-49. Specifically, the Complaint alleges that “Defendant [Orchid India], through its

subsidiary and agent [Orchid Delaware], submitted ANDA No. 90-044 to the U.S. Food and Drug Administration ('FDA') under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j))" seeking "FDA approval to market the Orchid Generic Products prior to the expiration of the '703 patent" and that the ANDA alleges that "the claims of the '703 patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of the Orchid Generic Products." *Complaint* at ¶¶ 45-46. Plaintiffs filed their Complaint on January 10, 2008. By agreement of the parties, Orchid was granted an extension until March 3, 2008, to respond to the Complaint.

## II. SUMMARY OF ARGUMENT

Defendant Orchid India moves to dismiss the claims asserted against it on the grounds that the Court lacks personal jurisdiction over Orchid India under Rule 12(b)(2). This Court lacks personal jurisdiction over Orchid India because the company has insufficient contacts with Delaware to satisfy the state's long-arm statute or the requirements of due process.

Delaware's long-arm statute provides for two types of personal jurisdiction: specific and general. 10 Del. C. § 3104. For purposes of specific jurisdiction, the cause of action must arise out of the defendant's activities within Delaware; for general jurisdiction a defendant is required to have "continuous and systematic contacts" with the state. *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 371 (D. Del. 2002) (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408 (1984)). Orchid India neither conducted activities within Delaware relating to the alleged cause of action, nor has continuous and systematic contacts with Delaware.

Like the case at hand, *Merck* involved a motion to dismiss for lack of personal jurisdiction brought by a foreign defendant in ANDA litigation. The plaintiff, Merck, conceded that specific jurisdiction was not available. *Id.* at 371. The Court found that general jurisdiction

was not available, as defendant Barr did not have persistent and substantial contacts with Delaware: it did not maintain offices, local telephone listings, or bank accounts in Delaware, did not have any employees in the state, and was not registered to do business with the Secretary of State. *Id.* at 374. Further, the Court found that an assertion of personal jurisdiction over Barr would violate the Due Process Clause, as Barr's business contacts with Delaware and its residents were not "continuous and systematic." *Id.* at 375.

The reasoning of *Merck* applies equally here. Orchid India is an Indian corporation with its headquarters in Chennai, India. *Affidavit of Dr. C. Bhaktavatsala Rao, February 29, 2008* ("Rao Aff."), at ¶ 2. Orchid India has no offices, property, or employees in Delaware, and sells no products in Delaware. *Id.* at ¶¶ 7, 9, 10. Orchid India has one wholly-owned Delaware subsidiary, Orchid Delaware. *Id.* at ¶ 4. Orchid Delaware is a holding company, and has no employees in Delaware. *Rao Aff.* at ¶ 4; *Affidavit of Mr. Satish Srinivasan, March 3, 2008* ("Srinivasan Aff."), at ¶ 4. It in no way participated in, contributed to, aided, abetted, or induced the submission of ANDA No. 90-044. *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8. Orchid India and Orchid Delaware preserve corporate formalities, and have separate accounting functions and books, separate bank accounts, separate employees, and entirely separate corporate identities. *Rao Aff.* at ¶ 12; *Srinivasan Aff.* at ¶¶ 5, 6. They are and hold themselves out to the public as separate entities. *Id.* Orchid Delaware has no power to bind Orchid India contractually or otherwise. *Rao Aff.* at ¶ 13; *Srinivasan Aff.* at ¶ 7.

In sum, Orchid Delaware is not Orchid India's alter ego or agent. Accordingly, whatever acts Orchid Delaware is being accused of, those acts cannot be imputed to Orchid India. Even if Orchid Delaware were to be considered Orchid India's alter ego or agent (which it is not), personal jurisdiction would *not* be established in this case because Orchid Delaware was not

involved in any activities giving rise to the alleged cause of action, *i.e.*, preparing and submitting ANDA No. 90-044.<sup>1</sup> *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8. Therefore, there are no relevant acts within Delaware that could be imputed to Orchid India to support jurisdiction.<sup>2</sup>

### III. STATEMENT OF FACTS

#### A. *Orchid India*

Orchid India is an Indian Corporation that is involved in the development and manufacture of active pharmaceutical ingredients and finished dosage forms, as well as in drug discovery. *Rao Aff.*, at ¶ 2. Orchid Healthcare, a Division of Orchid India, undertakes development and manufacture of finished dosage forms and the submission of ANDAs to FDA for such dosage forms. *Id.* at ¶ 3. Orchid India has no offices, facilities, telephone listings, bank accounts, or property in Delaware. *Id.* at ¶ 7. The company has no employees in Delaware and does not solicit business in Delaware. *Id.* at ¶¶ 7, 10. In addition, as a manufacturer of generic pharmaceuticals, Orchid India does not advertise its products directly to consumers in the United States. *Id.* at ¶ 9. Orchid India is not registered with the Secretary of State to do business in Delaware, and is not licensed by the State of Delaware to sell drugs in the state. *Id.* at ¶ 10. Orchid India does not sell products directly to retailers in the United States, but rather partners with other companies who are responsible for selling Orchid India's products in the United

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<sup>1</sup> Defendant Orchid Delaware intends to promptly move for summary judgment on the grounds that it did not "participate[] in, contribute[] to, aid[], abet[] and/or induce[] Orchid [Healthcare's] submission of ANDA No. 90-044 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA," and therefore did not infringe the '703 patent under 35 U.S.C. § 271(e)(2)(A). *Complaint* at ¶¶ 48-49; *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8.

<sup>2</sup> Orchid India and Orogenus have been sued in New Jersey in actions related to Orchid Healthcare's submission of ANDAs to the FDA covering other pharmaceutical compositions. *Rao Aff.* at ¶ 17; *Srinivasan Aff.* at ¶ 14. These entities are the proper defendants for any litigation arising under the Hatch-Waxman Act, as Orchid Healthcare (a division of Orchid India) is the Orchid entity responsible for submitting ANDAs and Orchid Healthcare named



States. *Id.* at ¶ 9. Orchid India has never sold any product in Delaware, and has never derived substantial revenues from sales within the state. *Id.* at ¶ 10. Orchid India has never commenced any legal action or proceeding in Delaware, nor has it previously been named a defendant in any action in Delaware. *Id.* at ¶ 11.

Orchid Healthcare submitted ANDA No. 90-044 to FDA on October 16, 2007 and named Orgenus Pharma, Inc. (“Orgenus”) as its U.S. regulatory agent. *Rao Aff.* at ¶ 14; *Srinivasan Aff.* at ¶¶ 10, 11 and Exhibit A thereto (*Letter to Orgenus Pharma, Inc., U.S. Agent for Orchid Healthcare*). Orgenus physically sent ANDA No. 90-044 to FDA from its office located in Princeton, New Jersey. *Srinivasan Aff.* at ¶ 11. Orgenus is a wholly-owned subsidiary of Orchid Delaware. *Id.* at ¶ 9. ANDA No. 90-044 was prepared by Orchid Healthcare and Orchid India in India. *Rao Aff.* at ¶¶ 3, 14, 15.

Orgenus publicly disclosed that it is Orchid Healthcare’s U.S. regulatory agent, as indicated in a Suitability Petition regarding generic 5 mg and 10 mg memantine hydrochloride orally disintegrating tablets submitted on behalf of Orchid Healthcare, which is publicly available on the FDA’s website.<sup>3</sup> *Srinivasan Aff.* at ¶ 13 and Exhibit B thereto.

#### **B. Orchid Pharmaceuticals, Inc.**

Orchid Delaware is a Delaware holding company, and has no employees in Delaware. *Srinivasan Aff.* at ¶ 4; *Rao Aff.* at ¶ 4. Orchid Delaware did not participate in, contribute to, or

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Orgenus as its U.S. regulatory agent for purposes of those ANDAs. Orchid India and Orgenus have not challenged jurisdiction in New Jersey. *Id.*

<sup>3</sup> See, e.g., Suitability Petition, dated May 18, 2007, available at <http://www.fda.gov/OHRMS/Dockets/Dockets/07p0203/07p-0203-cp00001-01-vol1.pdf> (“FDA Webpage”). The FDA Webpage indicates the information provided was last updated May 29, 2007, ten days after the FDA received Orgenus’ ANDA No. 90-044 and approximately six months before Forest Labs filed the present action.

otherwise aid in the preparation of ANDA No. 90-044 or in its submission to FDA. *Srinivasan Aff.* at ¶ 8; *Rao Aff.* at ¶ 16.

**C. *Orchid Pharmaceuticals, Inc. Is Not the Agent or Alter Ego of Orchid India***

Orchid Delaware is not the agent or alter ego of Orchid India. Orchid India and Orchid Delaware are, and hold themselves out to the public as, separate companies, and maintain all corporate formalities. *Rao Aff.* at ¶¶ 12, 13; *Srinivasan Aff.* at ¶¶ 4-7. The two companies have separate finances and bank accounts. *Rao Aff.* at ¶ 12; *Srinivasan Aff.* at ¶ 5. Orgenus is Orchid Healthcare's U.S. regulatory agent for ANDA No. 90-044, not Orchid Delaware. *Rao Aff.* at ¶ 14; *Srinivasan Aff.* at ¶¶ 10, 13. Orchid Delaware is not and does not represent itself as Orchid India's agent, and does not have the authority to bind Orchid India, contractually or otherwise. *Rao Aff.* at ¶¶ 12, 13; *Srinivasan Aff.* at ¶¶ 6, 7.

**IV. ARGUMENT**

Pursuant to Rule 12(b)(2), the Court may dismiss a lawsuit for failure to establish personal jurisdiction. For personal jurisdiction to exist over a non-resident defendant, two requirements must be met: one statutory and one constitutional. *Merck*, 179 F. Supp. 2d at 371. With regard to the statutory requirement, the Court must determine whether there is a statutory basis for jurisdiction under the forum state's long arm statute. *Id.* This first part of the analysis "must refer to state law even when underlying legal issues involve federal patent law." *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1462 (D. Del. 1991). As for the constitutional basis, the Court must determine whether the exercise of jurisdiction would comport with the defendant's right to Due Process. *Merck*, 179 F. Supp. 2d at 371 (citing *Int'l Shoe Co. v. Washington*, 326 U.S. 310 (1945)).

When a non-resident challenges personal jurisdiction, "the burden is on the plaintiff to show that the defendant ... purposefully availed itself of the privilege of conducting activities

within the forum State, thus invoking the benefits [and] protections of its laws.” *Virgin Wireless, Inc. v. Virgin Enterprises, Ltd.*, 201 F. Supp. 2d 294, 298 (D. Del. 2002). As such, the plaintiff may not rely on the pleadings alone to withstand a motion to dismiss for lack of personal jurisdiction. *Id.* Rather, “the plaintiff must come forward with facts to establish by a preponderance of the evidence that the court can exercise personal jurisdiction over the defendant.” *Id.*

Pursuant to the Delaware long arm statute, a non-resident defendant is deemed to have submitted to the jurisdiction of Delaware courts if the non-resident: (1) transacts any business or performs any character of work in the State; (2) contracts to supply services of things in the State; (3) causes tortious injury in the State by an act or omission in the State; (4) causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, or engages in regular conduct in the State, or derives substantial revenue from the State; (5) has an interest in, uses, or possesses real property in the State; or (6) contracts to insure or act as a surety for any person, property, risk, or contract located, executed, or to be performed within the State. 10 Del. C. § 3104(c)(1-6). “Specific jurisdiction arises when the particular cause of action arose from the defendant’s activities within the forum state; general jurisdiction arises when the defendant has continuous and systematic contacts with the state, irrespective of whether the defendant’s connections are related to the particular cause of action.” *Merck*, 179 F. Supp. 2d at 371 (citing *Helicopteros Nacionales*, 466 U.S. 408).

In this case, Plaintiffs have not established any basis for subjecting Orchid India to the jurisdiction of the Court under Delaware’s long-arm statute. Plaintiffs cannot demonstrate that Orchid India satisfies any of the criteria listed in Section 3104, and Plaintiffs cannot demonstrate

any connection at all between Orchid India and the State of Delaware. Orchid India is an Indian corporation that has no ties to Delaware, including no in-state offices, facilities, employees, telephone listings, real estate, or bank accounts. *Rao Aff.* at ¶¶ 2, 7. It does not solicit business in Delaware, and has never sold products or derived substantial revenues within the state. *Id.* at ¶¶ 9, 10. Because Plaintiffs have not and cannot show that Orchid India had any “minimum contacts” whatsoever with the State of Delaware, the exercise of personal jurisdiction over Orchid India would likewise offend the due process principles of “fair play and substantial justice.” *Merck*, 179 F. Supp. 2d at 375 (citing *Helicopteros Nacionales*, 466 U.S. at 416; *Provident Nat’l Bank v. California Fed. Savings & Loan Assoc.*, 819 F.2d 434, 437 (3d Cir. 1987)). Accordingly, the Court should grant Orchid India’s motion to dismiss for lack of personal jurisdiction.

**A. Plaintiffs Cannot Establish Specific Jurisdiction Over Orchid India**

Plaintiffs cannot establish specific jurisdiction because the cause of action at issue here did not arise from Orchid India’s activities within the State of Delaware. Subsections (c)(1) and (c)(3) of Delaware’s long-arm statute provide for specific jurisdiction, under which “the cause of action must arise from the contacts with the forum.” 10 Del. C. § 3104(c)(1,3); *see also Applied Biosystems*, 772 F. Supp. at 1466. A “jurisdictional act” is any act or omission committed by a defendant in Delaware that also causes tortious injury in Delaware, as required by Section 3104(c)(3). *Id.* Incorporating a subsidiary in Delaware provides specific jurisdiction over any tort causes of action related to the act of incorporation. *Sears, Roebuck & Co. v. Sears PLC*, 744 F. Supp. 1289, 1303 (D. Del. 1990). However, because Section 3104(c)(3) provides only for specific jurisdiction, the act of incorporation does not confer jurisdiction for unrelated torts. *Sears*, 744 F. Supp. at 1305; *Applied Biosystems*, 772 F. Supp. at 1467-68. Moreover, even

when tortious conduct by a subsidiary exists, it “does not alone justify an exercise of personal jurisdiction over the parent.” *Sears*, 744 F. Supp. at 1305.

Here, Plaintiffs cannot show that their purported cause of action for patent infringement arose “from [Orchid India’s] contacts with the forum.” 10 Del. C. § 3104(c)(1,3). Plaintiffs’ claim of patent infringement is based solely upon Orchid Healthcare’s submission of an ANDA to FDA under 35 U.S.C. § 271(e)(2)(A). *Complaint* at ¶¶ 45-49. Therefore the proper jurisdictional analysis focuses on the facts surrounding the preparation and submission of ANDA No. 90-044—acts that were undertaken by Orchid India in India and Orgenus in New Jersey. *Rao Aff.* at ¶¶ 3, 14, 15; *Srinivasan Aff.* at ¶ 11. Orchid Delaware was not involved in any way in the preparation or submission of the ANDA. *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8. As a result, a substantive connection to Delaware is entirely lacking.

In addition, there has been no injury to Plaintiffs in Delaware. The situs of the injury is the place where the patent holder suffers harm, *i.e.*, the patent holder’s principal place of business. *See, e.g., Applied Biosystems*, 772 F. Supp. at 1468; *Foster Wheeler Energy Corp. v. Metallgesellschaft AG*, C.A. No. 91-214-SLR, 1993 WL 669447 \*5 (D. Del. Jan. 4, 1993) (finding that any alleged injury would occur in New Jersey, the site of the plaintiff’s principal place of business, and not in Delaware, the state of incorporation). In this matter, the Merz entities assert that they own the ‘703 patent, and they are German corporations with their principal places of business in Frankfurt, Germany. *Complaint* at ¶¶ 3, 4, 27. Accordingly, any harm caused by Orchid Healthcare’s submission of ANDA No. 90-044 would be felt in Germany, not Delaware.

As a licensee, it is not clear that Forest Labs has independent standing to assert a claim under the ‘703 patent against a third party. *Complaint* at ¶ 28; *Textile Prods., Inc. v. Mead*

*Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) (finding that an exclusive licensee is not necessarily a “patentee,” and therefore may not have standing to sue third parties for patent infringement). However, even assuming Forest Labs does have sufficient rights in the ‘703 patent to possess standing, Forest Labs’ principal place of business is in New York—and therefore Forest Labs could not have suffered any injury in Delaware relating to Orchid India’s alleged infringement. *Complaint* at ¶ 1.

Thus, no jurisdictional acts took place in Delaware relating to Plaintiffs’ claims and the Plaintiffs have suffered no injury in the state. Consequently, Plaintiffs cannot meet their burden of establishing specific personal jurisdiction over Orchid India in Delaware.

**B. *Plaintiffs Cannot Establish General Jurisdiction Over Orchid India***

Plaintiffs also fail to meet their burden of establishing general jurisdiction under the Delaware long-arm statute. The general jurisdiction provisions of the Delaware long-arm statute allow jurisdiction where tortious injury occurs either in the State or outside the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State, or derives substantial revenue from services or things used or consumed in the State. 10 Del. C. § 3104; *Merck*, 179 F. Supp. 2d at 373. Thus the relevant inquiry for the purposes of this motion is whether Orchid India regularly does or solicits business, engages in any persistent conduct, or derives substantial revenue in Delaware. 10 Del. C. § 3104(c)(4); *Merck*, 179 F. Supp. 2d at 373. Orchid India has no such contacts with Delaware.

In *Merck & Co., Inc. v. Barr Labs., Inc.*, the District Court of Delaware considered whether it could assert personal jurisdiction over a New York corporation, Barr, in ANDA litigation. 179 F. Supp. 2d 368. The Court concluded that general jurisdiction was not available because the totality of Barr’s contacts with Delaware did not reach the level of persistence and



substantiality required. *Id.* at 374. Barr did not maintain offices, facilities, local telephone listings, or bank accounts in Delaware, did not own or lease any real property or employ any persons in Delaware, and was not registered with the Secretary of State to do business in Delaware. *Id.* However, Merck argued that Barr was subject to general jurisdiction because it maintained two licenses in Delaware to distribute and sell products within the state, made yearly payments to Medicaid, sold its drugs directly to a pharmacy for retail sale in Delaware, and sold and distributed approximately \$1.2 million worth of the drug Viaspan<sup>®</sup> through LHSI, its “agent.” *Id.*

The Court found that Barr had only minimal contacts with Delaware and the actions of LHSI could not be attributed to Barr because the Court was not persuaded LHSI was Barr’s agent. *Id.* at 373. The Court also determined that Barr itself did not derive substantial revenues within Delaware, and Barr’s sales to corporations with national distribution were not relevant because the nexus was too attenuated. *Id.* The Court noted that the general jurisdiction provision of Section 3104(c)(4) did not anticipate that placing a product into the stream of commerce would give rise to jurisdiction. *Id.* at 373-74.

The Court’s grant of defendant’s motion to dismiss in *Merck* compels an identical result in this case. Orchid India is an Indian corporation that has no contacts with Delaware—no offices, real property, telephone listings, bank accounts, or employees. *Rao Aff.* at ¶¶ 7-11. It does not sell any product in Delaware and does not solicit sales in this State. *Id.* It is not registered with the Secretary of State to do business in Delaware and is not licensed by the State of Delaware to sell drugs within the State. *Id.* Moreover, Orchid Delaware is not an agent of Orchid India, and the presence of the latter within the state of Delaware is not sufficient to establish personal jurisdiction over Orchid India. *Sears*, 744 F. Supp. at 1305; *Applied*

*Biosystems*, 772 F. Supp. at 1467-68. Moreover, Orchid Delaware was not even involved in the preparation or submission of ANDA No. 90-044. *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8.

Therefore, Plaintiffs have not satisfied their burden of establishing general personal jurisdiction over Orchid India in Delaware.

**C. *There Is No Personal Jurisdiction Over Orchid India Based on the Existence of Its Subsidiary, Orchid Delaware***

Delaware courts regularly decline to “lightly set aside corporate formalities in order to hail a foreign corporation into this judicial district.” *ICT Pharmas., Inc. v. Boehringer Ingelheim Pharmas., Inc.*, 147 F. Supp. 2d 268, 274 (D. Del. 2001). However, Delaware law provides two theories under which a court may establish jurisdiction over a foreign parent corporation based on jurisdiction over a subsidiary: alter ego and agency. *Applied Biosystems*, 772 F. Supp. at 1463 (citations omitted). Neither of these theories are applicable in this case.

**1. Orchid Delaware Is Not Orchid India’s Alter Ego**

In order to establish personal jurisdiction over a parent corporation under the alter ego theory, the plaintiff must establish some “fraud, injustice, or inequity in the use of the corporate form.” *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 559 (D. Del. 1998). Application of the alter ego theory is often referred to as “piercing the corporate veil.” *Id.* Delaware courts have found that the alter ego theory does not apply where the two corporations maintain corporate formalities, including separate boards of directors, employees, accounting systems, bank accounts, tax returns, etc. *Id.* at 558. In *C.R. Bard*, for example, the Court found no basis for exercising jurisdiction over Defendant under the alter ego theory because there was no evidence of “fraud in the corporate structure” of the defendants. *Id.*

Orchid Delaware is not the alter ego of Orchid India. The two companies hold themselves out to the public as separate corporations, and maintain corporate formalities. *Rao*



*Aff.* at ¶¶ 12, 13; *Srinivasan Aff.* at ¶¶ 6, 7. They have separate finances and bank accounts. *Rao Aff.* at ¶ 12; *Srinivasan Aff.* at ¶ 5. Orchid Delaware does not represent itself as Orchid India's agent, and does not have the authority to bind Orchid India, contractually or otherwise. *Rao Aff.* at ¶ 13; *Srinivasan Aff.* at ¶ 7. Moreover, Orchid Delaware is a holding company that has no employees or revenues, and takes no corporate actions which could be attributed to Orchid India. *Srinivasan Aff.* at ¶¶ 4-8. Accordingly, Plaintiffs cannot establish jurisdiction over Orchid India based on the alter ego theory.

**2. Orchid Delaware Is Not Orchid India's Agent, and Therefore Its Conduct Cannot Be Imputed to Orchid India**

A court can assert personal jurisdiction over "a parent company, for the acts of its subsidiaries, to the extent that the actions of the subsidiaries are 'directed and controlled' by the parent." *Sears, Roebuck & Co. v. Sears PLC*, 752 F. Supp. 1223, 1226 (D. Del. 1990) (citing *Altech Indus., Inc. v. Al Tech Specialty Steel Corp.*, 542 F. Supp. 53 (D. Del. 1982)). However, only the "precise conduct shown to be instigated by the parent" can be attributed to the parent. *C.R. Bard*, 997 F. Supp. at 560; *see also Applied Biosystems*, 772 F. Supp. at 1467. Even if the acts are indeed "directed and controlled" by the parent, however, a court cannot exercise jurisdiction over claims unless the alleged violations by the non-Delaware subsidiaries are sufficiently related to the conduct in Delaware. *Sears*, 752 F. Supp. at 1226. For jurisdiction to "arise from" an act, it must have been a "critical step in the chain of events" resulting in the cause of action before the court. *Id.* at 1227. It is the acts giving rise to the claim, and not the nature of the claim, that determines whether a cause of action arises from contacts within the forum. *Id.* In other words, there must be a causal connection between the act or omission and the cause of action. In the present case, Orchid India neither "directed and controlled" the

actions of Orchid Delaware, nor did Orchid Delaware have any connection to the actions giving rise to the alleged cause of action.

The decision in *Monsanto Company v. Syngenta Seeds, Inc.*, is instructive. In *Monsanto*, Syngenta filed an antitrust action against Monsanto, alleging that they had monopolized markets for genetically modified corn seed. 443 F. Supp. 2d 636, 638 (D. Del. 2006). Monsanto counterclaimed against Syngenta AG and several of its subsidiaries. Syngenta AG was a Swiss holding company whose business consisted primarily of owning shares in companies. *Id.* at 638. One of Syngenta AG's wholly-owned subsidiaries, Syngenta Corporation, was a Delaware holding company that owned (either directly or indirectly) the other defendants named in the counterclaims. *Id.* at 639. The Court found that an overlap of officers and directors, shared employees, and Syngenta AG's involvement in strategic decisions were *insufficient* to establish an agency relationship under Delaware law. *Id.* at 644. "The mere fact that a non-Delaware corporation owns a Delaware subsidiary is not sufficient in itself to justify Delaware's exercise of personal jurisdiction over the non-Delaware parent." *Id.* at 645. The Court granted Defendant's motion to dismiss for lack of personal jurisdiction because it had not "engaged in a pattern of corporate dealings under Delaware law." *Id.* at 646-47.

Similarly, Orchid India is a foreign corporation with no contacts in Delaware. As the *Monsanto* Court recognized, the mere fact that Orchid Delaware is incorporated in Delaware is insufficient to establish personal jurisdiction over Orchid India, as the cause of action is unrelated to Orchid Delaware's incorporation and Orchid Delaware's status as a Delaware corporation cannot be imputed to Orchid India. *See Monsanto*, 443 F. Supp. 2d at 646. Moreover, none of the accused acts occurred in Delaware, nor was Orchid Delaware connected in any way to the accused acts. While personal jurisdiction may be proper over Orchid India in

New Jersey based on Orgenus' acts within that state, the agency theory cannot be distorted to change the location of the conduct in question to Delaware. Orgenus' acts in New Jersey as U.S. regulatory agent for Orchid Healthcare cannot be considered Orchid Delaware's or Orchid India's acts in Delaware. Accordingly, the assertion of personal jurisdiction over Orchid India in Delaware is improper.

**3. None of the Orchid Entities Committed Any Acts in Delaware Sufficient to Establish Personal Jurisdiction over Orchid India**

Even if actions of a subsidiary could be attributed to the parent through the agency or alter ego theories, jurisdiction would exist only if those actions were a "critical step in the chain of events" resulting in the cause of action. *See, e.g., Sears*, 752 F. Supp. at 1226. Here, there is *no* causal connection between any conduct by Orchid Delaware and Plaintiffs' claims. Orchid Delaware was not involved in the preparation or submission of ANDA No. 90-044. *Rao Aff.* at ¶ 16; *Srinivasan Aff.* at ¶ 8. As a result, Orchid Delaware cannot not be properly accused of infringing the '703 patent under Section 271(e)(2). 35 U.S.C. § 271(e)(2)(A); *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612, 616 (D. Del. 2004) (a claim for infringement of an ANDA requires proof of direct infringement and cannot be based solely upon allegations of aiding and abetting the filing of the ANDA). In short, neither Orchid India nor any of its subsidiaries committed any acts in Delaware that are related to the present cause of action. Accordingly, the assertion of personal jurisdiction over Orchid India is contrary to Delaware's long arm statute.

**D. *Exercise of Jurisdiction over Orchid India in this Matter Would Violate Due Process***

The essential due process inquiry "asks whether the defendants have had sufficient minimum contacts with the forum to satisfy 'traditional notions of fair play and substantial justice.'" *Applied Biosystems*, 772 F. Supp. at 1470 (*quoting Int'l Shoe*, 326 U.S. 310 (citation

omitted)). The constitutionality of an exercise of personal jurisdiction turns on whether the defendant has “purposefully directed” its activity toward the forum state. “If so, and if the litigation arises out of those activities, the defendant may have established the requisite minimum contacts with the forum despite the lack of any physical contacts.” *Applied Biosystems*, 772 F. Supp. at 1470. “For an assertion of general jurisdiction to be constitutional, the defendant must have developed ‘continuous and systematic’ contacts with the forum state.” *Id.* at 1470 (citing *Helicopteros Nacionales*, 466 U.S. at 416).

The Court in *Merck & Co., Inc. v. Barr Labs., Inc.*, found that the requirements of due process were not satisfied because Barr’s business contacts with Delaware and its residents were not “continuous and systematic.” *Id.* at 375. The Court found that Barr had not availed itself of Delaware resources, in that it had no employees, bank accounts, or real estate and did not solicit business in Delaware. *Id.* The *Merck* Court further found that “mere ownership [of a Delaware subsidiary] is insufficient to establish substantial activities in Delaware.” *Id.* The Court concluded that Delaware had no interest in adjudicating the case, as the cause of action did not involve “Delaware related claims or Delaware plaintiffs.” *Id.*

Assertion of personal jurisdiction over Orchid India by a Delaware court would likewise be contrary to the Due Process Clause. The Due Process inquiry focuses on the nature of contacts defendants have with the forum state. Orchid India cannot be said to have “purposefully directed” any activities towards Delaware, as it does not do any business within the state, has no employees in Delaware, and has no “continuous and systematic” contacts with the state. *Rao Aff.* at ¶¶ 7-11. Orchid Delaware is not an agent or alter ego of Orchid India, and therefore its conduct cannot be imputed to Orchid India. Indeed, as noted above, Orchid Delaware did not

commit any jurisdictional acts related to the present action to be imputed. Therefore, exercise of personal jurisdiction in Delaware over Orchid India is improper.

## V. CONCLUSION

For the reasons stated herein, Defendant Orchid India respectfully requests that the allegations against it be dismissed for lack of personal jurisdiction.

Respectfully submitted,

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Dated: March 3, 2008  
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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

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